



June 9, 2014

Federal Trade Commission
Office of the Secretary
Room H-113 (Annex J)
660 Pennsylvania Avenue, NW
Washington, DC 20580

SUBMITTED ELECTRONICALLY

Re: Spring Privacy Series: Consumer Generated and Controlled Health Data, Project No. P145401

ACT respectfully submits the following comments regarding the Federal Trade Commission's ("FTC") workshop on Consumer Generated and Controlled Health Data on May 7, 2014 ("May 7th event").

ACT | The App Association is the leading organization representing over 5,000 small and mid-sized software companies in the mobile app ecosystem. Our members build the apps consumers use every day, at home, at work, and at play. As consumer use of mobile devices increases, privacy and security are increasingly important. ACT appreciates the opportunity to submit comments.

As the app industry has grown rapidly over the last few years, the emergence of the mobile health market has been equally impressive. The global mobile health market was estimated at \$1.2 billion in 2011 and is projected to increase to \$11.8 billion by 2018.¹ The health apps share of that market was \$150 million in 2012 and analysts expect this to grow 23 percent annually over the next five years.²

Patients, healthcare providers, and the healthcare industry are increasingly turning to mobile apps that use consumer generated and controlled health data to provide better patient care.

The U.S. Food and Drug Administration ("FDA") has made a distinction between health apps--like BMI calculators and fitness trackers--and medical apps which have specific clinical implications.³

¹ Harry Greenspun and Sheryl Coughlin, "mHealth in a mWorld: How mobile technology is transforming health care," Deloitte Center for Health Solutions, 12 (2012) *available at* http://www.deloitte.com/assets/Dcom-UnitedStates/Local%20Assets/Documents/us_chs_2012_mhealth_HowMobileTechnologyIsTransformingHealthCare_032213.pdf.

² *Id.* at 13.

³ "Mobile Medical Applications" FDA (last visited 9 June 2014) *available at* <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ConnectedHealth/MobileMedicalApplications/default.htm>.

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Health Apps are the Next Frontier

The FTC has focused its attention on health apps as more consumers look to use mobile devices to stay healthy. With a smartphone, users can connect to their physician from anywhere in the world and provide diagnostic data. Phones and tablets now serve as a platform connecting medical devices that allow patients to monitor their blood pressure, glucose levels, and other vital statistics at home and transmit this data daily to a health care provider.

Mobile devices are also able to connect physicians with those in underserved communities, remote areas, or with limited mobility for whom office visits are difficult and occur infrequently. With connected wireless devices providing more and more diagnostic data, doctors can spot the early signs of adverse conditions and take preventive measures to improve health outcomes.

Mobile health apps provide benefit to three distinct groups of users: healthcare consumers, healthcare professionals, and the healthcare industry. While these three groups use medical information differently, they all benefit from consumer generated and controlled health data.

Healthcare Consumers

Healthcare consumers are the most conspicuous group of health app users. In 2012, over 247 million users had downloaded a health app to their mobile device.⁴ These apps can monitor our steps, weight loss, sleep, and even pregnancy. They provide a way for consumers to be directly involved in their own healthcare and provide valuable data to their healthcare providers.

For example, mobile health company Withings produces a number of wearable devices, such as the Withings Pulse and Wireless Blood Pressure Monitor. These devices connect to an app on a mobile device that allows consumers to take measurements and monitor their progress. This information is stored on a mobile device, providing users with detailed history they can share with healthcare professionals.

In places where doctors can be hard to reach, mobile apps provide a needed connection and information to patients all over the world, including in developing countries. Close to 90 percent of the world's population have wireless coverage and 65 percent of cell phone subscribers reside in developing countries.⁵ Mobile apps provide healthcare information to rural areas and can track and address health epidemics.

⁴ *Supra* note 1 at 13.

⁵ "Mobilizing a revolution: How cellphones are transforming public health," Harvard School of Public Health Magazine (Winter 2012), *available at* <http://www.hsph.harvard.edu/news/magazine/mobilizing-a-revolution/>.



Healthcare Professionals

Where physicians previously consulted a mobile device just to quickly look up a medical term, mobile apps are now providing the physicians with personalized patient information that can be used to make diagnoses, monitor progress, and directly connect with patients. Mobile apps allow a care team to better engage with a patient, keeping doctors informed on patient status to help foster recovery. Physicians can prescribe health apps and medical tracking devices, like blood pressure cuffs and heart rate monitors that connect to mobile devices and apps. Over a third of U.S. physicians have prescribed a patient an app.⁶

Mobile apps also facilitate better communication between patients and providers to produce better health outcomes. Utah-based Orca Health provides healthcare professionals with brilliant images and graphics of the human body on a mobile platform to help explain to patients the nature and location of their injury or illness and the process for fixing it.⁷ The 3D images give patients a better understanding of their medical conditions and allow them to make more informed healthcare decisions.

Medical professionals also use apps to make their jobs easier. Doctors use mobile devices and apps to monitor their patients and review charts. Texas-based AirStrip provides software that allows doctors and other medical professionals with access to patient medical information like x-rays, CT scans, and vital statistics in near real time. Remote access to this information allows doctors to quickly assess patient conditions and determine a course of treatment, allowing them to react to any change in the patient condition and meet the need of expanding patient populations.

Mobile apps help make telemedicine a reality for patients and reduces the problem of geography. Interknowlogy, a San Diego-based company, has created an app using Microsoft's Kinect that allows patients to perform their rehabilitation exercises at home and reports their progress to their healthcare team, even allowing a patient's healthcare team to monitor the patient's exercise remotely.⁸ Ensuring that patients are properly performing physical therapy exercises helps speed recovery while reducing healthcare costs for patients, doctors, and the healthcare industry.

⁶ Jonah Comstock, "Survey: One third of docs recommend a health app to patients," *Mobi Health News* (29 May 2014) *available at* <http://mobihealthnews.com/33594/survey-one-third-of-docs-recommended-a-health-app-to-patients/>.

⁷ Orca Health (last visited 9 June 2014) *available at* <https://orcahealth.com/features>.

⁸ Interknowlogy Solutions Rehab With Kinect (last visited 9 June 2014) *available at* <http://www.interknowlogy.com/solutions/#rehab-with-kinect>.



Healthcare Industry

The healthcare industry is embracing mobile apps as a way to better serve their consumers. Mobile apps are used to reduce medical costs of patients, monitor progress of clinical trials, and reduce paperwork for billing, scheduling, and claims processing.

The healthcare industry turns to companies like Ideomed to provide medical apps to their consumers that assist in wellness objectives that also lower healthcare costs. Ideomed, a Michigan-based company, uses daily engagement through mobile apps to improve health outcomes of chronically ill patients through daily engagement. With an estimated 75 percent of every healthcare dollar spent on chronic conditions, Ideomed looks to address the real economic need for a less expensive way to proactively address chronic illnesses.

Ideomed CEO Keith Brophy testified before Congress that Ideomed's web and mobile-based engagement platform Abriiz has made a significant impact in addressing the chronic condition of asthma.⁹ Abriiz is a health management platform that helps monitor patient medication compliance and track asthma symptoms. Data from a yearlong pilot test indicates Abriiz was able to significantly lower emergency room visits. Ideomed understands the information collected by its apps is sensitive and takes steps to protect its users' data.

"An ounce of prevention is worth a pound of cure;" a sentiment that the healthcare industry is embracing with mobile apps. Health insurance companies are looking to mobile platforms like Abriiz; keeping patients healthy helps to reduce costs, an outcome that benefits everyone.

Best Practices for the Mobile Health Industry

As the mobile health industry continues to grow, it is critical that privacy and security safeguards are implemented with regard to patient data. John Wald, the medical director for the Mayo Clinic's public affairs and marketing operation noted that, "[i]f we lose that trusted aspect, we've lost everything. We are committed to maintaining that trust."¹⁰ The industry breakthroughs in wellness and patient outcomes through mobile devices makes clear that comprehensive studies are needed before regulatory actions are considered.

⁹ "Testimony of Keith Brophy, Chief Executive Officer, Ideomed" House Committee on Small Business Subcommittee on Health and Technology (27 June 2013) *available at* http://smallbusiness.house.gov/uploadedfiles/6-27-2013_brophy_testimony.pdf.

¹⁰ Evan Schuman, "Apple's new HealthKit app has some important questions to answer," mHealth News (4 June 2014) *available at* <http://www.mhealthnews.com/news/apples-new-healthkit-app-has-some-important-questions-answer?page=0>.



Transparency in Oversight and Regulations

The FTC and other agencies have existing regulatory requirements for companies in the mobile health industry. The best approach to Health IT safety combines elements of public-private partnership to guide industry with best practices that conform to all applicable privacy laws.

Recently, a combined effort between federal agencies including the FDA, Federal Communications Commission (“FCC”), and U.S. Department of Health and Human Services (“HHS”) resulted in the release of the Food and Drug Administration Safety and Innovation Act (“FDASIA”) report on health IT and its impact on mobile health apps.¹¹ The report concluded that the functionality, and not platform, should be the key regulatory determinate when addressing mobile apps.

ACT | The App Association strongly supports the report's recommendation to create a Health IT Safety Center. Convening stakeholders to identify sustainable, innovative health IT systems is critical and our members will provide significant input through this open and transparent process. Privacy should be a key focus of FDASIA IT Center as it provides guidance in the mobile health space.

Industry Working to Protect Consumer Generated Health Data

The FTC has appropriately raised concerns for mobile health privacy which industry is meeting in real time. Many stakeholders have been actively involved in providing training and guidance on best practices around mobile health apps privacy and security.

Recently ACT | The App Association joined with CEA, CTIA, mHIMSS, the National Venture Capital Association, the American Telemedicine Association, Continua Health Alliance, Johns Hopkins University Global mHealth Initiative, Stanford University Biodesign Program, and many others on a Mobile Medical App Roadshow across the country.¹² Roadshow participants spoke to auditoriums filled with app makers, providing guidance to attendees about the regulatory landscape and best practices of the mobile health industry.

mHIMSS also hosts privacy and security forums around the country addressing health data.¹³ The Center for Democracy & Technology’s (“CDT”) Health Privacy Project works to protect consumer

¹¹ FDASIA Health IT Report (3 April 2014) *available at* <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm390588.htm>.

¹² “2014: The Year of the Mobile Medical Revolution,” (7 Jan. 2014) *available at* <http://actonline.org/2014/01/2014-the-year-of-the-mobile-medical-revolution/>.

¹³ mHIMSS Events (last visited 9 June 2014) *available at* <http://www.himss.org/Events/index.aspx?EventType=1988>.



healthcare data through studies, events, and guidance. There are many more industry-led educational efforts and events committed to protecting consumer health data.¹⁴

Mobile platforms are also undertaking efforts to provide a safe and secure environment for mobile health apps. In its next mobile operating system—iOS 8—Apple will feature HealthKit, a valuable tool for developers in the mobile health and wellness space.¹⁵ It will provide a single, secure place for users to store medical and fitness data, making it easier to build better apps and for consumers to track and secure their health data.

The healthcare and user data in HealthKit is stored securely and using encryption. By restricting apps from selling user health information to advertisers, Apple is creating a platform that users can trust with their sensitive medical and health data. Users can control their data and restrict what information is shared with a specific app and also prevent apps from seeing what information the user has chosen to block. With HealthKit, consumers have complete control over their health information.

The mobile health industry understands it is critically important to ensure the privacy and security of patient data. Nowhere is consumer trust more important than when a consumer allows an app to generate and control their health data. In the competitive app industry, mobile health solutions stand out by providing an app or mobile solution that consumers trust with their health data.

The FTC’s Fair Information Practice Principles (FIPPs) privacy guidelines have provided some guidance regarding protection of consumer generated and controlled health data. In addition, industry best practices and standards offer additional insights to those providing services for the intersection of consumer products and their healthcare provider. As Commissioner Ohlhausen said, FIPPs “remains a solid framework and is flexible enough to accommodate a robust big data industry.”¹⁶

Better Health App Studies Needed

ACT | The App Association understands the FTC’s interest in the privacy and security of mobile health apps, as expressed by the May 7th event. However, it is clear that more comprehensive studies are needed on the safety and security of mobile health apps.

The staff observations on mobile apps presented at the May 7th event contained a sample size of only 12 apps; far too small to get the full view of the mobile health app industry. With over 31,000

¹⁴ Other mobile health events include the mHealth and Telehealth World Congress (<http://www.worldcongress.com/events/HL14028/>), the Digital Health Summit (<http://digitalhealthsummit.com/>), and the mHealth Summit (<http://www.mhealthsummit.org/>).

¹⁵ See iOS 8 Preview Health (last visited 9 June 2014) *available at* <https://www.apple.com/ios/ios8/health/>.

¹⁶ Remarks by Commission Maureen Ohlhausen at Georgetown University (22 April 2014) *available at* <http://www.ftc.gov/public-statements/2014/04/power-data>.



mobile health apps available to consumers, there needs to be a more comprehensive look at the industry.¹⁷

FTC Authority to Oversee Health Mobile Apps and Protect Consumers

The FTC already has authority under Section 5 to address any abuses in the mobile health space. That authority has allowed the FTC to address the bad practices of mobile apps such as Snapchat.¹⁸ In this and other instances, the FTC has used its enforcement authority against apps which do not conform to their privacy policies. Such authority can and should be used against health apps which violate their privacy policies and misuse consumer information.

In addition, other federal agencies such as the HHS and FDA are already working to regulate mobile health apps. Most recently, the FDA released guidance regarding the regulation and certification of health apps.¹⁹

Conclusion

The mobile health industry is a vibrant and growing industry that allows healthcare professionals and industry to better serve patients using consumer generated and controlled health data. Because this data is sensitive, the industry continues to work on best practices to better protect and secure that information while still providing innovative apps for consumers.

We appreciate the FTC's support and leadership in this field and ACT looks forward to working with the FTC on industry best practices. With transparent guidance and support, the mobile health industry will continue to grow and provide patients the best possible care available.

¹⁷ Michael Essany, "Mobile Health Care Apps Growing Fast in Number" mHealth Watch (15 April 2013) *available at* <http://mhealthwatch.com/mobile-health-care-apps-growing-fast-in-number-20052/>.

¹⁸ "Snapchat Settles FTC Charges That Promises of Disappearing Messages Were False," FTC (8 May 2014) *available at* <http://www.ftc.gov/news-events/press-releases/2014/05/snapchat-settles-ftc-charges-promises-disappearing-messages-were>.

¹⁹ *Supra* note 3.